2001, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for treating a viral infection by administering a dose of interferon which is in excess of a dose of the same interferon which induces a pathological response when parenterally administered, and the dose is greater than 20×10^6 IU for a 70 kg human. The interferon is administered to a mammal which has a viral infection and is used for treating the infection, as opposed to mere prophylaxis. The oromucosal administration is in a manner which does not involve direct action of the interferon on virally infected cells. Furthermore, when the condition is a rhinovirus, the interferon is not administered through the mouth by multiple or continuous dosages.

The telephone interview between Examiner Goldberg and the undersigned attorney on January 24, 2002, is hereby gratefully acknowledged. In this interview, the examiner stated that the language of the last two lines of claim 36 (amended) was not acceptable to define over Eby because the term "single dose" does not define over a continuous dose. It was pointed out to the examiner, however, that the specification indicated a clear distinction between a "single" dose and a "continuous dose", such as at page 6, lines 5-10, of the present specification. In order to avoid ambiguity in

this regard, the undersigned suggested that the language "the interferon is administered in a single dose" be changed to read "the interferon is not administered in a multiple or continuous dose". The examiner agreed that this would eliminate the ambiguity and be sufficient to define over Eby as far as claim 36 was concerned. The examiner pointed out, however, that Japanese abstract 06-298665, submitted in applicant's Information Disclosure Statement appeared to anticipate claim 36 as it comprehended antiviral treatment by nasal administration of interferon at a dosage of 50 to 9×10^6 units. While it is not believed that the nasal administration proposed in this patent comprehends oromucosal administration, nevertheless, in order to obviate this rejection, claim 36 has been amended to specify that the dose of interferon administered was greater than about 20×10^6 IU of interferon for a 70 kg human, as had previously appeared in claim 21. Accordingly, claim 21 has now been deleted. The examiner agreed that with this amendment, claim 36 would be allowable over the references of record.

With respect to claim 37, the examiner stated that, while the language "greater than 20×10^6 IU of interferon" was sufficient to avoid anticipation in view of Eby's maximum of 20,000,000 IU, the examiner considered it obvious to one of

ordinary skill in the art reading Eby to use 1 IU more than 20,000,000 IU and expect it also to be active.

The undersigned argued that Eby teaches the extremely wide dosage range of 1-20,000,000 IU and that one would expect such a dosage range to cover only that which was active. In other words, one would expect a bell curve of activity with the optimum activity at about 10,000,000 IU, but that one would not expect any activity below 1 IU or greater than 20,000,000 IU. Alternatively, one would assume that the side effects would be too great above 20,000,000 IU. When an applicant inserts such a large range, those of ordinary skill in the art would assume that it includes everything which is active. Therefore, there would be no motivation for one of ordinary skill in the art to use even one IU more than 20,000,000 IU. The examiner stated that this argument was convincing and that he would withdraw the rejection of claim 37. Applicant advised that a new set of claims similar to claims 22-35 would be added ultimately dependent from claim 37. This includes claims such as new claim 48 which specifies that the minimum dosage is 50×10^6 IU, which is patentable in its own right because of the even larger difference between the minimum claimed dose and the maximum claimed dose of Eby. Accordingly, it is believed that, as a result of this interview and the present amendment, the rejections of record

have been overcome and the case should be in condition for allowance.

Claims 21-37 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Eby III. This rejection is respectfully traversed.

As discussed hereinabove, Eby states at column 5, lines 27-53, that in order to be effective his administration must be by mouth and not by administration to the interior of the nose, and it must be administered in a sustained way and not in single dose. Thus, the provisos in the last two lines of claim 36 define over Eby. As Eby teaches that the administration must be in a sustained way, it would not be obvious to introduce in a single dose which is not a multiple or a continuous dose and, as Eby states that it cannot be administered by nose, the administration intranasally is not anticipated by Eby.

With respect to claim 37, this has been discussed hereinabove with respect to the discussion of the contents of the interview. With respect to claims 30 and 31, these claims have now been amended such that the minimum does not contradict the minimum in the claims from which they depend.

Accordingly, all of the present claims define over Eby for the reasons discussed in the interview.

Reconsideration and withdrawal of this rejection as agreed in the interview are, therefore, respectfully urged.

Claims 21-36 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification. The examiner states that the term "a rhinoviral infection, the interferon is administered in a single dose or is administered intranasally by multiple or continuous doses" fails to find basis in the specification as filed. This rejection is respectfully traversed.

The examiner's attention is invited to page 6, lines 5-10, of the present specification, which reads:

> The oromucosal administration may involve administering an effective dose of interferon in a single dose or the effective dose may be administered in a plurality of smaller doses over a period of time sufficient to elicit immunostimulation equivalent to that of a single dose. Likewise, the dose of interferon may be administered continuously over a period of time sufficient to induce an effect equivalent to that of single dose.

Furthermore, the examiner's attention is invited to page 12, lines 11-19, which states:

> The IFN may be administered by any means which provides contact of the IFN with the oromucosal cavity of the recipient. Thus it will be clearly understood that the invention is not limited to any particular type of formulation. The present specification describes administration of IFN deep into the oromucosal cavity; this

> may be achieved with liquids, solids, or aerosols, as well as nasal drops or sprays. Thus the invention includes, but is not limited to, liquid, spray, syrup, lozenges, buccal tablets, and nebulizer formulations. A person skilled in the art will recognize that for aerosol or nebulizer formulations the particle size of the preparation may be important, and will be aware of suitable methods by which particle size may be modified.

Thus, the present specification clearly encompasses the species of administration in a single dose, as well as the species of administration in multiple or continuous doses. Further, the present specification clearly includes the species of administering oromucosally through the nose or oromucosally through the mouth. As each of these species are disclosed, there is written description for a sub-genus of fewer than all of these specified species. Claim 36 has now been amended to specify that the interferon is not administered in a multiple or continuous dose. This is supported by the above-quoted portion of page 6 of the specification. It further states that the interferon is administered intranasally by multiple or continuous doses. As indicated in the above-quote portion of page 12, the species of intranasal administration is supported, as is the species of multiple or continuous dose. Therefore, this language is supported in the present speciation sufficient to comply with the written description requirement of 35 U.S.C. §112. Note

that provisos eliminating disclosed species of a claimed genus to avoid reading on the prior art were held to comply with the written description requirement in *In re Johnson*, 194 USPQ 187, 196 (CCPA 1977). Reconsideration and withdrawal of this rejection are, therefore, respectfully urged.

It is submitted that all of the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are, therefore, earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

Respectfully submitted,

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In re of Appln. No. 09/243,030

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Rae Dethlefsen
Name

Rae Dethlefsen
Signature

January 25, 2002
Date

Version with Markings to Show Changes Made

Claims 22-25, 30-33 and 36 have been amended as follows:

22 (Amended). The method of claim ~~36~~ 37 in which the effective dose of interferon is administered in a single dose.

23 (Amended). The method of claim 37~~36~~, in which the effective dose of interferon is administered in a plurality of smaller doses over a period of time sufficient to elicit a response equivalent to that of a single dose.

24 (Amended). The method of claim 37~~36~~, in which an effective dose of interferon is administered continuously over a period of time sufficient to elicit a response equivalent to that of a single dose.

25 (Amended). The method of claim 37~~36~~, wherein the interferon comprises a Type I interferon.

28 (Amended). The method of claim 37~~36~~, wherein the interferon comprises a Type II interferon.

30 (Amended). The method of claim 37~~36~~, wherein the dose of interferon is ~~from about 20 x 10^6 IU~~up to about 1000 x 10^6 IU of interferon.

31 (Amended). The method of claim 37~~36~~, wherein the dose of interferon is ~~from about 20 x 10^6 IU~~ up to about 500 x 10^6 IU of interferon.

32 (Amended). The method of claim 3736, wherein the dose of interferon is from about 50 x 10^6 IU to about 500 x 10^6 IU of interferon.

33 (Amended). The method of claim 3637, wherein the viral infection is selected from the group consisting of rhinovirus, influenza, herpes varicella, herpes zoster, dengue fever, viral encephalitis, haemorrhagic fever, genital herpes, equine morbillivirus, hepatitis B, hepatitis C, hepatitis D, CMV, HIV, HPV, HSV- I and HSV-2.

34 (Amended). The method of claim 33, wherein said viral encephalitis is selected from the group consisting of measles virus encephalitis, Murray Valley encephalitis, Japanese B encephalitis, tick-borne encephalitis and Herpes encephalitis.

35 (Amended). The method of claim 33, wherein said haemorrhagic fever is selected from the group consisting of Ebola virus, Marburg virus, Lassa fever, and Hanta virus infections.

36 (~~Amended~~Twice-amended). A method for treating a viral infection, which method comprises administering to the mammal having such a viral infection an effective amount of ~~an interferon~~ greater than about 20 x 10^6 IU of interferon for a 70 kg human via oromucosal contact, said amount being in excess of a dose of the same interferon which induces a

pathological response when parenterally administered, said oromucosal administration being in a manner which does not involve direct action of the interferon on virally infected cells and provided that when the viral infection is a rhinoviral infection, the interferon is not administered in a ~~single~~ multiple or continuous dose or is administered intranasally by multiple or continuous ~~doses~~dose.

Claim 21 has been deleted.

New claims 38-51 have been added.